

§ 201.161 Carbon dioxide and certain other gases.

(a) Carbon dioxide, cyclopropane, ethylene, helium, and nitrous oxide gases intended for drug use are exempted from the requirements of § 201.100(b) (2), (3), and (c)(1) provided the labeling bears, in addition to any other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The warning statement "Warning—Administration of (name of gas) may be hazardous or contraindicated. For use only by or under the supervision of a licensed practitioner who is experienced in the use and administration of (name of gas) and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications, and side effects and the precautions to be taken"; and

(2) Any needed directions concerning the conditions for storage and warnings against the inherent dangers in the handling of the specific compressed gas.

(b) This labeling exemption does not apply to mixtures of any one or more of these gases with oxygen or with each other.

(c) Regulatory action may be initiated with respect to any article shipped within the jurisdiction of the Act contrary to the provisions of this section after 60 days following publication of this section in the FEDERAL REGISTER.

Subpart F—Labeling Claims for Drugs in Drug Efficacy Study**§ 201.200 Disclosure of drug efficacy study evaluations in labeling and advertising.**

(a)(1) The National Academy of Sciences—National Research Council, Drug Efficacy Study Group, has completed an exhaustive review of labeling claims made for drugs marketed under new-drug and antibiotic drug procedures between 1938 and 1962. The results are compiled in "Drug Efficacy Study, A Report to the Commissioner of Food and Drugs from the National Academy of Sciences (1969)." As the report notes, this review has made "an audit of the state of the art of drug usage that has

been uniquely extensive in scope and uniquely intensive in time" and is applicable to more than 80 percent of the currently marketed drugs. The report further notes that the quality of the evidence of efficacy, as well as the quality of the labeling claims, is poor. Labeling and other promotional claims have been evaluated as "effective," "probably effective," "possibly effective," "ineffective," "ineffective as a fixed combination," and "effective but," and a report for each drug in the study has been submitted to the Commissioner.

(2) The Food and Drug Administration is processing the reports, seeking voluntary action on the part of the drug manufacturers and distributors in the elimination or modification of unsupported promotional claims, and initiating administrative actions as necessary to require product and labeling changes.

(3) Delays have been encountered in bringing to the attention of the prescribers of prescription items the conclusions of the expert panels that reviewed the promotional claims.

(b) The Commissioner of Food and Drugs concludes that:

(1) The failure to disclose in the labeling of a drug and in other promotional material the conclusions of the Academy experts that a claim is "ineffective," "possibly effective," "probably effective," or "ineffective as a fixed combination," while labeling and promotional material bearing any such claim are being used, is a failure to disclose facts that are material in light of the representations made and causes the drug to be misbranded.

(2) The Academy classification of a drug as other than "effective" for a claim for which such drug is recommended establishes that there is a material weight of opinion among qualified experts contrary to the representation made or suggested in the labeling, and failure to reveal this fact causes such labeling to be misleading.

(c) Therefore, after publication in the FEDERAL REGISTER of a Drug Efficacy Study Implementation notice on a prescription drug, unless exempted or otherwise provided for in the notice, all